
**SYSTEM, METHOD, AND COMPUTER PROGRAM PRODUCT FOR PROCESSING
DIAGNOSTIC, TREATMENT, COSTS, AND OUTCOMES INFORMATION FOR
EFFECTIVE ANALYSIS AND HEALTH CARE GUIDANCE**

U.S. Patent Application of:

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[0001] Cross-Reference to Other Application

This application claims priority from copending U.S. Patent Application 09/212,521, filed 12/16/1998 (MM/DD/YYYY), which is hereby incorporated by reference.

[0002] Technical Field

The present application relates to an improved method for health care. In particular, the present application relates to an improved system and method for computer-assisted medical diagnostics and reporting.

[0003] Description of the Related Art

Allocation of health care resources to individuals in a cost effective manner without compromise to outcomes and quality has become a significant issue in contemporary society. A movement exists to establish standards of care to assure that the highest quality of medicine is practiced in a uniform manner. These standards of care may include written protocols and practice guidelines or priority and appropriateness rankings promulgated by organizations, and/or priorities of diagnostics and treatment to be followed by individual health care providers. To successfully establish standards of care, however, diagnostic and treatment information must be both successfully captured in a form suitable for effective analysis and provided, to the health care provider at the point of decision.

[0004] The capture of diagnostic and treatment information is impeded by the extreme degree of complexity associated with outcome data and their measurement and reliability. While theoretical models attempt to simplify the measurement tools for outcome analysis, outcomes are not simply “cured” versus “not cured” propositions, but instead include variables driven by issues such as quality of life, increased longevity, complications, and side effects. To compensate, some

methodologies factor such variables into the outcome measurement to derive “quality adjusted” results. This factoring makes it difficult to formulate specific recommendations for individual cases.

5 [0005] Currently, ICD9 codes, which are general descriptions of the disease process, and CPT and DRG billing codes are the only information typically available for analysis of individual diagnostic-treatment cycles. Attempts to retrospectively obtain data necessary for effective analysis, such as the rationale for a particular treatment choice, is extremely difficult since such information is not normally captured. Thus medical societies, which typically gather only measurement data, and the insurance industry, which is substantially constrained to analyzing information provided with billing records, are generally unable to obtain this information for analysis.

15 [0006] Early attempts at an Electronic Medical Record have taken the form of simply converting the paper chart to a paperless chart contained in a medical electronic medical record database. Since much of the record is in text form, analysis of clinical data is hampered by inconsistent data entry, the absence of relationships between the data collected, and the lack of consistent vocabularies allowing comparison between and among systems. Consistent data fields are largely demographic in nature rather than oriented to clinical research. While the need for consistent database fields to support data analysis has been recently recognized, and some medical societies are developing outcome study databases for the relevant specialty, no effort has been undertaken to capture specific and accurate clinical and cost information for diagnostics and treatments based on specific disease issues. Such information is necessary for effective analysis both within specialties and globally across all specialties. Clinical and costs analyses of outcome data would benefit both the health care profession and insurance providers.

25 [0007] For effective use, clinical and cost information from prior diagnostic-treatment cycles must also be provided to health care professionals at the point of decision. Customary practices are difficult to influence or alter without the ability to offer suggestions at the time the customary practice is performed.

Summary of the Invention

[0011] It is therefore one object of the present invention to provide an improved method for health care.

[0012] It is another object of the present invention to provide an improved an improved system and method for computer-assisted medical diagnostics and reporting.

[0013] The foregoing objects are achieved as is now described. The preferred embodiment provides a computer-assisted system and method that guides health-care providers through a diagnostic decision-making process, including giving the providers guidance as to a treatment program which conforms to medically-accepted practice and health industry insurance practices. The preferred embodiment guides the health care provider in entering protocol, diagnostic, and treatment choices in a natural manner that corresponds to a mental diagnostic and treatment process, and also checks diagnoses and treatments against appropriateness rules according to protocol choices and test results entered for each patient. The data entered is processed to process and audit clinical procedures and costs.

[0014] The above as well as additional objectives, features, and advantages of the present invention will become apparent in the following detailed written description.

Brief Description of the Drawings

[0015] The novel features believed characteristic of the invention are set forth in the appended claims. The invention itself however, as well as a preferred mode of use, further objects and advantages thereof, will best be understood by reference to the following detailed description of illustrative sample embodiments when read in conjunction with the accompanying drawings, wherein:

[0016] **Figure 1** depicts a data structure containing diagnostic and treatment information in accordance with a preferred embodiment of the present invention;

[0017] **Figure 2A** is an entity relationship diagram for a relational database employed in formulating a diagnostic and treatment information data structure in accordance with a preferred embodiment of the present invention;

[0018] **Figure 2B** is an object Oriented Database Management System Model diagram employed in formulating a diagnostic and treatment information data structure in accordance with a preferred embodiment of the present invention;

[0019] **Figure 3** depicts a high level flowchart for a process of formulating a diagnostic and treatment information data structure in accordance with a preferred embodiment of the present invention;

[0020] **Figures 4A-4C** are user interface diagrams for a software application for formulating a diagnostic and treatment information data structure in accordance with a preferred embodiment of the present invention;

[0021] **Figure 5** is a diagram of a data processing system network in which the diagnostic and treatment information data structure in accordance with a preferred embodiment of the present

invention may be employed; and

[0022] **Figure 6** is a flowchart of a process in accordance with a preferred embodiment of the present invention.

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Detailed Description of the Preferred Embodiments

5 [0023] The numerous innovative teachings of the present application will be described with particular reference to the presently preferred embodiment (by way of example, and not of limitation).

10 [0024] The preferred embodiment provides a computer-assisted system and method that guides health-care providers through a diagnostic decision-making process, including giving the providers guidance as to a treatment program which conforms to medically-accepted practice and health industry insurance practices. The preferred embodiment includes information regarding a particular diagnosis-treatment cycle for an individual patient. The diagnostic and treatment information data structures for a number of diagnosis/treatment cycle may be combined within a database for analysis in outcomes or cost effectiveness studies. A relational database which assists the health care provider in formulating the diagnostic and treatment information data structure for a specific diagnosis-treatment cycle may, within a user interface, display information determined during the outcomes or cost effectiveness studies to influence the health care provider at the point of decision, and may serve to satisfy the documentation requirements being mandated by regulatory organizations. Effective analyses of diagnostic, treatment, and outcomes information and guidance for health care professionals based on such analyses is thus facilitated. An Internet/intranet database program employing the diagnostic and treatment information data structure contains both clinical and financial information permitting effective filtering of CPT codes as to accuracy and appropriateness.

20 [0025] The parent of the present application relates generally to capturing diagnostic and treatment information for individual diagnosis-treatment cycles and in particular to capturing such diagnostic and treatment information in a form suitable for effective analysis across multiple diagnosis-treatment cycle instances and providing guidance to a health care provider at the point of decision in a subsequent diagnosis-treatment cycle. Still more particularly, the parent relates to a novel data structure capturing cost information, protocol treatment choices and rationales together with initial disease variable values and outcomes to permit both effective analysis and development

of treatment guidelines. Codes may be effectively transferred onto the superbill and may be employed to facilitate or bypass the authorization process for insurance companies. Codes may provide an effective means of transferring data between dissimilar health and billing information systems, and for documenting the health care process to facilitate regulatory guideline compliance.

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10 [0026] With reference now to the figures, and in particular with reference to **Figure 1**, a data structure containing diagnostic and treatment information in accordance with a preferred embodiment of the present invention is depicted. Data structure **102** encapsulates demographic, location, physician, specialty, testing, diagnostic, and treatment information concerning a particular diagnosis-treatment cycle for an individual medical problem experienced by an individual patient. Data structure **102** includes a plurality of subcodes or fields including disease variable(s) (vcode) field **104**, protocol choice justification field **106**, diagnostic/treatment procedure(s) justification field **108**, and CPT variable field **110**.

15 [0027] Vcode field **104** contains a unique code for a set of critical disease variables **112a-112n** adapted for the specialty of the health care provider performing the diagnosis-treatment cycle for the respective patient. Different specialties rely on different diagnostic information in selecting treatment. In breast cancer, for example, tumor margins are of important significance to the surgical and radiation oncologists, but less important to the medical oncologist; menopausal status, on the other hand, is of substantially greater importance to the medical oncology specialty than to the surgical and radiation oncology specialties. Accordingly, the critical disease variables **112a-112n** employed to generate the contents of vcode field **104** are selected from the overall patient diagnostic testing information depending on the specialty of the health care provider. The group of approximately 3-7 critical disease variables **112a-112n** employed is preselected based on the standard practices of the corresponding specialty.

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[0028] The test results from corresponding tests on the patient are entered into disease variables **112a-112n**, and the ranges within which the test results fall are encoded as a unique code in vcode field **104**. The data entered into disease variables **112a-112n** is also employed to select a protocol

grouping for various possible treatment protocols. For this purpose, possible test results for each disease variable **112a-112n** should be grouped based on specified ranges or cutoff information supported by outcomes research. For instance, with respect to prostate cancer, the pathologic Gleason grading of 3 to 10 may be grouped into four ranges for that variable: Gleason 3-4, Gleason 5-6, Gleason 7, and Gleason 8-10. These aggregates are supported by outcomes research in prostate cancer. Therefore, an actual measured result (e.g., Gleason 6) would be compared to these ranges and employed to select a protocol grouping **114a-114n**.

[0029] Other critical variables for prostate cancer for radiation therapy include the disease stage, the patient's age, and the PSA blood value. However, as the number of disease variables and/or ranges within a disease variable increases, the number of possible protocol groupings also increases. The number of unique permutations possible for all disease variables can thus quickly grow to between about 250 and 500 combinations. While this number of permutations is manageable for analysis and reporting, it is hardly useful for diagnosis and treatment. Therefore, each possible combination of disease variables is assigned to one of approximately 10-12 protocol groupings **114a-114n**, roughly correlating to the generally accepted diagnostic practices of most members of the relevant specialty. In practice, the protocol groupings are preferably formulated and/or approved by the professional medical society associated with the relevant specialty, in a manner analogous to the limited efforts undertaken in the American College of Radiology's Appropriateness Criteria Project. Rather than addressing only a limited number of variants, however, a comprehensive treatment of all possible permutations is preferred within protocol groupings **114a-114n**.

[0030] Each protocol grouping **114a-114n** includes all possible diagnostic/treatment regimes warranted by the values for disease variables **112a-112n**, together with a corresponding priority assigned to the regime within that protocol grouping. Every protocol grouping **114a** through **114n** need not necessarily contain all possible diagnostic and treatment regimes, since governing medical standards will, in certain circumstances, rule out particular treatment regimes as entirely inappropriate given the measured test results in disease variables **112a-112n**. However, protocol groupings **114a-114n** are not intended to limit the health care provider's choice of treatment regimes.

Therefore, even low percentage treatments (those which produce favorable outcomes in only a small fraction--say, 5% or less-of cases) for a given set of values in disease variables **112a-112n** are included in the appropriate protocol grouping. The priorities assigned to the diagnostic and treatment regimes within a specific protocol grouping reflect the statistical probabilities of success determined through outcomes research.

[0031] The health care provider then chooses a diagnostic and treatment protocol from the protocol grouping selected based on the disease variable values. A code for the protocol choice selected and the associated priority for that protocol within the relevant protocol grouping may optionally be stored in protocol choice field (not shown). The health care provider is also prompted to enter a justification code **106**, which reflects the rationale of the health care provider in selecting the chosen protocol. Justification code **106** is selected from a predefined set designated by the appropriate professional society, and uniquely identifies the protocol selected as well as the particular rationale for selecting the chosen protocol. Justification code **108** may include, for example, a code for a rationale such as "highest priority" to reflect that the selected protocol rates the highest priority in the relevant protocol grouping, "symptoms" to indicate that the health care provide believes the treatment is warranted by the symptoms, or "upper range(s)" to reflect that one or more disease variables is close to the next highest range employed to select protocol groupings.

[0032] Once the diagnostic or treatment regime (protocol) has been selected, the health care provider next selects particular diagnostic and/or treatment procedures from the selected protocol, together with a justification code from predefined sets **118a-118n** for each procedure within the selected protocol. As with protocol justification codes, a particular procedure justification code uniquely identifies both the procedure selected and the rationale of the health care provider for selecting a procedure. The justification code entered by the health care provider for each diagnostic or treatment procedure selected is stored in procedure(s) justification field **108**. Thus, procedure(a) justification field **108** may contain one or more codes, each for a different diagnostic or treatment procedure.

[0033] Finally, a CPT or DRG variable code **110** is included in data structure **102**. CPT variable code **110** is a billing code identifying the procedures performed. Again, the appropriate professional society may develop the variants of the CPT codes which are employed. CPT code inaccuracy and abuse detection is enabled since the availability in the present invention of disease and protocol variables for cross-matching with CPT code variables permits significant analysis and filtering of CPT codes.

[0034] Referring to **Figure 2A**, an entity relationship diagram for a relational database employed in formulating a diagnostic and treatment information data structure in accordance with a preferred embodiment of the present invention are illustrated. Data structure **102** encapsulating the diagnostic-treatment information is preferably formed through a structured data entry process in which a consistent vocabulary is employed. A relational database is preferably employed to guide the data entry process.

[0035] **Figure 2A** depicts an entity relationship diagram for an exemplary relational database utilized to guide the health care provider in entering a protocol choice and justification into the appropriate fields of the diagnostic and treatment information data structure. The "Protocol Text" table is the parent table from which the protocol groupings are obtained for a particular specialty, and includes the fields listed below in Table I:

Protocol Text: Table		
Field Name	Data Type	Description
ProtocolCode	Text	Unique code for protocol
ProtocolDescription	Text	Protocol Grouping description
ProtocolMemo	Memo	Expanded information on grouping
ProtocolOLE	OLE Object	
ICD9	Text	
Specialty	Text	

Table I

[0036] The "ProtocolMemo" field provides additional information which may be selectively viewed by the health care provider, such as a description of the factors which influenced the decisions regarding priority assignments within the respective protocol group.

[0037] The disease variables V1 through V10 are input into a child table "Internet Suffix", which includes the fields listed below in Table II:

Internet Suffix: Table		
Field Name	Data Type	Description
VCode	Text	Shortened code of suffix
ICD9Suffix	Text	Defined suffix
ICD9	Text	ICD9 Code
Specialty	Text	Medical specialty
V1	Text	Variable #1
V2	Text	Variable #2
V3	Text	Variable #3
V4	Text	Variable #4
V5	Text	Variable #S
V6	Text	variable #6
V7	Text	Variable 07
V9	Text	Variable #8
V9	Text	Variable 09
V10	Text	Variable #10
Update	Date/Time	Date updated field
ProtocolCode	Text	

Table II

[0038] The “Internet Suffix” table determines the “Wodell for the disease variable combinations, and also determines the appropriate ICD9 code. The appropriate protocol grouping may then be displayed for the user to make a protocol choice.

[0039] The “Protocol Choice” child table generates codes for the user-selected protocol choice to be entered into the protocol choice code field of the diagnostic and treatment information data structure with the fields listed in Table III:

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Protocol Choice: Table		
Field Name	Data Type	Description
ProtocolChoiceCode	Text	Unique code of protocol
ProtocolCode	Text	
ProtocolChoice	Text	Label of choice
ProtocolChoiceDescription	Text	
ProtocolChoiceOLE	OLE Object	
ProtocolChoicePriority	Text	Priority score from medical society
ProtocolCodeHyperlink	Hyperlink	

Table III

[0040] A justification for the selected protocol choice is obtained from a "Protocol Justifications" child table including the fields listed in Table IV:

Protocol Justification: Table		
Field Name	Data Type	Description
ProtocolJustificationCode	Text	Unique code
ProtocolJustification	Text	
ProtocolChoiceCode	Text	
ProtocolChoiceDescription	Text	
ProtocolJustificationInfo	Memo	
ProtocolJustificationOLE	OLE Object	

Table IV

[0041] As part of the selection of a protocol, the health care provider may specify particular treatments or diagnostic tests within the protocol grouping selected. The specific diagnostic test(s) and/or treatment(s) specified, together with a justification code for those diagnostic test(s) and/or treatment(s), are input into the “Protocol Text” table from the “TestOrRx Table” child table and from the “TRx Justification Table” child table, which include the fields listed in Tables V and VI, respectively:

TestOrRx Table: Table		
Field Name	Data Type	Description
TestOrRx	Text	
ProtacolCode	Text	
TRxCode	Text	
Priority	Text	
PriorityInfo	memo	
Grouping	Text	
Category	Text	
TestRxHyperlink	Hyperlink	

Table V

TRX Justification Table: Table		
Field Name	Data Type	Description
TRXJustification	Text	
TRxCode	Text	
TRxJustificationCode	Text	
TRxInfo	Text	
TRxOLE	OLE Object	

Table VI

[0042] The individual diagnostic and treatment regimes within the protocol grouping which are selected by the health care provider are justified and encoded into the protocol choice and justification fields of the diagnostic and treatment information data structure.

[0043] Finally, a "CPTVariableCode" table with the fields listed in Table VII below provides the CPT variable code. These codes described the specific variables utilized in deriving the correct billing charge (CPT code).

CPTVariableCode: Table		
Field Name	Data Type	Description
VCPTCode	Text	
CPT	Text	
Specialty	Text	
TechOrProf	Text	
Category	Text	
VCPT1	Text	
vCPT2	Text	
vCPT3	Text	
vCPT4	Text	
vCPT5	Text	
vCPT6	Text	

Table VII

[0044] The relational database described above provides the analysis tool and may also be employed for the data entry user interface. The various code definitions employed may be modelled as an object oriented database for Internet presentation

[0045] Referring to **Figure 2B**, an Object Oriented Database Management System Model diagram employed in formulating a diagnostic and treatment information data structure in accordance with a preferred embodiment of the present invention is illustrated. The user interface screen capture shown in Figure 2B illustrates the hierarchical arrangement of database fields for protocols. The background screen capture illustrates a hierarchy for prostate cancer ("ProstateRO"), under which are the disease variables ("Variables", including "Stage", "Gleason" and "PSA"), the Vcodes ("VCodes"), the protocol definitions ("SPProtocols"), and the treatment and testing regimes ("RxTests", including "BoneScans" and "CTPelvis"). The protocol groupings ("SPProtocols") on the left maps to a number of protocol definitions ("PR1Ext1", "PR1Ext2", "PR1Ext3", "PR1Ext3", "PR2Ext1", "PR2Ext2", etc.) on the right. Additionally, the hierarchy may include insurance company billing and authorization information ("InsuranceCo").

[0046] The screen capture in the foreground of **Figure 2B** illustrates the information forming a protocol definition (specifically "PR1Ext1"). This includes the protocol code ("SPProtocolCode"), priority ("SPPriority"), and description ("SPDescription"), the defined justification codes ("SPJustifications"), information regarding outcomes study results and cost effectiveness ("SPInformation"), and insurance information ("InsuranceCo").

[0047] With reference now to **Figure 3**, a high level flowchart for a process of formulating a diagnostic and treatment information data structure in accordance with a preferred embodiment of the present invention is depicted. The process begins at step 302, which depicts data entry into a diagnostic and treatment information data structure being initiated. The process then passes to step 304, which illustrates retrieving test result values of the relevant disease variables for the specialty under which the data entry is being performed and determining the appropriate protocol grouping. The set of disease variables is defined for each specialty and the test values may be extracted, for example, from an electronic patient record. The test values are compared to defined ranges as described above to determine which protocol grouping is appropriate. Each disease variable code uniquely identifies a single protocol grouping to which the disease variable ranges map. The protocol grouping, listing diagnostic and treatment protocols in order of priority, may then be

displayed to the user.

5 [0048] The process next passes to step 306, which depicts prompting the user for the protocol choice justification. The protocol choice is not automatic, but must be selected by the health care provider. The justification selected uniquely identifies both the protocol selected by the health care provider and the rationale for making such selection. The protocol choice justification need only be selected once for a particular disease process.

10 [0049] The process passes next to step 308, which illustrates a determination of whether the user has selected a protocol choice justification. If not, the process returns to step 308 to continue awaiting user selection of a protocol choice justification. if so, however, the process proceeds instead to step 310, which depicts prompting the user for diagnostic or treatment procedure(s) justification(s) for the diagnostic and treatment procedures selected by the health care provider. The different diagnostic and treatment procedure (s) justification (s) may be entered over a period of time, recorded as each diagnosis and/or therapy is undertaken.

15 [0050] The process next passes to step 312, which illustrates a determination of whether the user has completed selection of procedure(s) justification(s) for the specific diagnostic test and treatments selected within a protocol choice. If not, the process returns to step 312 to continue awaiting user entry of additional justifications. if so, however, the process proceeds instead to step 314, which depicts determining the correct CPT variable code. The CPT variable code may be a composite of multiple CPT codes, each for a different diagnostic or treatment procedure.

20 [0051] The process then passes to step 316, which illustrates combining codes for: (1) the disease variable value ranges; (2) the protocol choice justification selected by the user; (3) the specific diagnostic testing and treatment procedures justifications selected by the user; and (4) the CPT variant determined by the CPT codes for the diagnostic and treatment procedures performed. These code may be combined as discrete objects within a container object or as either a delimited character string or a single character string code having defined field sizes. The character strings representing

the combined codes may be electronic, printed, or both. A code identifying the medical service provider and specialty may be appended. The process finally proceeds to step 318, which depicts the process becoming idle until data entry is again initiated for a diagnostic and treatment information data structure in accordance with the present invention.

[0052] The process depicted in **Figure 3** is merely exemplary for the purposes of explaining the present invention, and those skilled in the art will recognize that numerous variants are possible. Procedures depicted as combined in a single step in the example of **Figure 3** may be performed separately, and procedures depicted as separate steps may be combined. The order in which procedures are performed is not critical, except where a particular portion of the process is dependent on a prior portion. No limitations are intended to be implied by the example shown.

[0053] Referring to **Figures 4A-4C**, user interface diagrams for a software application for formulating a diagnostic and treatment information data structure in accordance with a preferred embodiment of the present invention are illustrated. The user interface diagrams shown are for a software application employing an object-oriented database of the type described above in connection with **Figure 2** and Tables I-VII and performing a process substantially similar to that shown in **Figure 3**.

[0054] A first user interface display 402 contains a plurality of disease variable data entry fields 404 defined for the relevant specialty, in which the test values for the disease variables V1, V1, V3, etc. through V10, if necessary, may be entered. A user control 406, which is a button in the depicted example, causes the software to operate on the entered variable values to determine the corresponding protocol grouping, which may be displayed as ProtocolCode 408 and VCode 410. A second user control 412, a hyperlink in the depicted example, allows the user to view a display containing the protocol choices, priorities, and justifications for the identified protocol grouping.

[0055] Actuation of user control 412 causes the software to display a second user interface display 414 containing protocol choice information groupings 416a-416m. Each protocol choice

information grouping **416a-416n** includes, for the protocol grouping identified by ProtocolCode **408**, a ProtocolChoiceCode field **418** displaying the protocol choice code for the corresponding protocol choice, a ProtocolChoiceDescription field **420** displaying a brief description of the corresponding protocol choice, a ProtocolChoicePriority field **422** displaying the priority of the corresponding protocol choice within the identified protocol grouping, a display **424** of information regarding the corresponding protocol choice and/or comparative information with respect to other protocol choices within the identified protocol grouping, and a display **426** of defined, justifications for the corresponding protocol choice.

[0056] The user may select a protocol choice and justification within those displayed for the identified protocol grouping by actuating a pointing device while a cursor (not shown) is displayed within an area of the user interface display **412** occupied by the protocol choice information grouping **416a-416n** associated with the desired protocol choice. A visual cue as to the user's protocol choice selection may be provided, by highlighting the ProtocolChoiceCode field **418** of the selected protocol choice. A user control **428** is provided for the user to submit the selected protocol choice. The user will then be prompted to select a justification code from those listed in display **426**.

[0057] Actuation of user control **428** causes the software to display a third-user interface display **430** containing specific diagnostic or treatment regime information **432** for the selected protocol choice. This will include, for instance, justifications for selecting particular diagnostic or treatment procedures. It appropriate, user interface display **430** may also display the CPT code **434** and description **436** for the selected protocol choice and diagnostic and treatment regime, as well as the CPT variable code **438**.

[0058] The software application employing the user interfaces described above and depicted in **Figures 4A-4C** guides the health care provider through data entry for a diagnostic and treatment information data structure in accordance with the present invention. It also provides an opportunity to guide the health care providers decision by identifying medically-accepted priorities for particular protocol choices given disease variable values and supplying direct and/or comparative information

for each protocol choice which is dependent on the disease variable values. This information may include outcomes study results, cost effectiveness information, or other suitable information.

[0059] With reference now to **Figure 5**, a diagram of a data processing system network in which the diagnostic and treatment information data structure in accordance with a preferred embodiment of the present invention may be employed is depicted. Data processing system network **502** includes a health care provider data processing system **504** in which the diagnostic and treatment information data structure of the present invention is formulated for a particular diagnosis-treatment cycle. Data processing system **504** is coupled by communications link **506** to the Internet **508**, which is coupled in turn to medical society data processing system **512** by communications link **510** and to insurance company data processing system **516** by communications link **514**. Insurance company data processing system **516** may be any suitable server system, and may relate to private insurance, to a benefits plan such as Medicare, or to other similar systems. Data processing systems **504**, **512**, and **516** and communications links **506**, **510** and **514** may be any suitable data processing system or communications link known in the art.

[0060] With data processing system network **502**, the diagnosis and treatment information data structure for a particular diagnosis treatment cycle may be shared by the health care provider with the relevant medical society or societies and the insurance company or companies. According to the preferred embodiment, no patient-identifying information is contained within the diagnosis and treatment information data structure of the present invention, thus protecting the patient's confidentiality, although, of course, patient-identifying information can be combined in or with the data to allow for patient-specific accounting. The diagnosis and treatment information data structures for various diagnosis-treatment cycles may be collected and combined in a database for analysis. Since the underlying disease variable information, the rationale of the health care provider, and the outcomes measurements for a specific diagnosis-treatment cycle are all available within each diagnosis and treatment information data structure, the information may be effectively analyzed utilizing known statistical methods to determine effectiveness, outcomes probabilities, and absolute or relative cost effectiveness.

[0061] Medical societies for specialties treating particular diseases, such as breast cancer, prostate cancer, lung cancer, colon/rectum cancer, the lymphomaa, diabetes, congestive heart failure, asthma, and the like may each maintain databases of diagnosis and treatment information data structures submitted by members or insurance companies. These databases may be employed to define or refine protocol groupings and the protocol choice priorities within each protocol groupings. Periodic review may be performed to generate updates provided to members and to attempt to identify previously undiscovered trends.

[0062] Insurance companies may employ the collected data to perform cost analyses and to assist in negotiating capitated contracts. Compensation schemes for particular protocol choices and justifications may be established, such as requiring patient payment for treatments which have low probabilities of success but which are chosen by the patient over other treatments having higher probabilities of success. importantly, the CPT variable code may be cross-correlated and checked against the protocol choice and selected diagnosis and treatment procedures for inaccuracy or appropriateness.

[0063] Health care providers may be provided within information from medical societies or insurance companies within the user interface of applications formulating the diagnosis and treatment information data structure for a particular patient. This information may thus be brought to influence the health care provider at the point of decision. Regional and national outcomes information, as well as treatment variant success rates, may also be accessed by the health care provider in selecting a protocol choice.

[0064] **Figure 6** shows a flowchart of a computer-aided health care decision process in accordance with the preferred embodiment. First, data entry is initiated on a data processing system (**step 602**) by starting a computer program according to the preferred embodiment. Next, the health care provider will enter a patient identifier into the data processing system (**step 604**). Next, the health care provider will enter disease and/or test result variable codes into the data processing system (**step**

606). As this is done, corresponding protocol groupings, with appropriate diagnostic and treatment protocols, are displayed to the health care provider (**step 608**).

5 [0065] This processes mimics the health care provider's natural thinking process as he or she uses the variable codes to define the state of the patient. As the data is entered, the displayed diagnostic and treatment protocols are specifically tailored, using the protocol groupings and disease and protocol variable codes, to display a customized protocol choice listing to the health care provider, in step 608.

10 [0066] Next, the health care provider will enter a protocol choice and justification (**step 610**) which uniquely identifies both the protocol selected by the health care provider and the rationale for making such selection. The protocol choice justification need only be selected once for a particular disease process.

15 [0067] Next, the health care provider will enter one or more diagnostic/treatment codes and corresponding justification (**step 612**) to indicate a diagnoses or proposed treatment of the patient. As he or she does so, the data processing system will check each entry against a database of previous entries and a "rules" list of standard reasonable and necessary diagnoses and treatments corresponding to each protocol grouping, and indicate to the health care provider whether or not the entry is typical for a patient in this condition (**step 614**). It should be noted that this process will not
20 "disapprove" any diagnoses or treatment, but will "flag" them as diverging from the rules list. The justification entered by the health care provider should justify the treatment, whether so flagged or not. Of course, the different diagnostic and treatment procedure(s) justification(s) may be entered over a period of time, recorded as each diagnosis and/or therapy is undertaken, so not all data entry
25 for a specific patient will necessarily be done in one session.

[0068] The data processing system will then combine codes for: (1) the disease variable value ranges; (2) the protocol choice justification selected by the user; (3) the specific diagnostic testing and treatment procedures justifications selected by the user; and (4) the CPT variant determined by

the CPT codes for the diagnostic and treatment procedures performed (**step 616**). These code may be combined as discrete objects within a container object or as either a delimited character string or a single character string code having defined field sizes. The character strings representing the combined codes may be electronic, printed, or both. A code identifying the medical service provider and specialty may be appended. These codes, as well as all the other data recorded for this patient, is stored for later reference (**step 618**).

[0069] The data stored for each patent is later read and processed for many different functions (**step 620**), including billings, audits of costs, audits of whether the diagnoses and tests performed were reasonable, necessary, and properly justified, evaluations of whether “flagged” procedures were justified, and others. As this data is stored in data structures in accordance with the preferred embodiment, many of these functions can be performed efficiently, quickly, and in an automated fashion. The flagged entries, in particular, make it easy for unusual procedures to be easily identified and examined for cost, appropriateness, and effectiveness.

[0070] The process described above therefore allows the health care provider to enter disease variables, protocol justifications, diagnoses, treatments, and corresponding justifications in a natural manner that reflects the typical mental process in diagnosing a patient. As the health care provider enters data, the system will display corresponding diagnoses, treatments, and indications as to whether the provider’s choices correspond to typical treatments.

[0071] The process depicted in **Figure 6** is merely exemplary for the purposes of explaining the present invention, and those skilled in the art will recognize that numerous variants are possible. Procedures depicted as combined in a single step in the example of **Figure 6** may be performed separately, and procedures depicted as separate steps may be combined. The order in which procedures are performed is not critical, except where a particular portion of the process is dependent on a prior portion. No limitations are intended to be implied by the example shown.

[0072] It should be noted that while the data entry is performed on a local data processing system, corresponding to health care provider system **504** in **Figure 5**, the data is not necessarily stored there,

but may be stored on another system on network 502. For example, in one embodiment, the data is entered into a computer program product executing on system 504, stored on system 504, then later sent to or retrieved by another system on network 502. In another embodiment, the computer program product actually resides on another system, for example insurance system 516, and data entry is performed by the health care provider remotely on system 504, which transmits and receives data over network 502 with system 516.

[0073] The description of the preferred embodiment of the present invention has been presented for purposes of illustration and description, but is not intended to be exhaustive or limit the invention in the form disclosed. Many modifications and variations will be apparent to those of ordinary skill in the art. The embodiment was chosen and described in order to best explain the principles of the invention and the practical application to enable others of ordinary skill in the art to understand the invention for various embodiments with various modifications as are suited to the particular use contemplated.

[0074] It is important to note that while the present invention has been described in the context of a fully functional data processing system and/or network, those skilled in the art will appreciate that the mechanism of the present invention is capable of being distributed in the form of a computer usable medium of instructions in a variety of forms, and that the present invention applies equally regardless of the particular type of signal bearing medium used to actually carry out the distribution. Examples of computer usable mediums include: nonvolatile, hard-coded type mediums such as read only memories (ROMs) or erasable, electrically programmable read only memories (EEPROMs), recordable type mediums such as floppy disks, hard disk drives and CD-ROMs, and transmission type mediums such as digital and analog communication links.